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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,757	07/28/2003	Yasuhiro Kouchi	Q76319	3310

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EXAMINER	
SITTON, JEHANNE SOUAYA	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 12/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/627,757	Applicant(s) KOUCHI ET AL.	
	Examiner Jehanne S. Sitton	Art Unit 1634	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 November 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *none*.
   Claim(s) objected to: *none*.
   Claim(s) rejected: *1, 4, 5*.
   Claim(s) withdrawn from consideration: *none*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

Continuation of 5. Applicant's reply has overcome the following rejection(s): the rejection under 35 USC 112/first paragraph: Written Description made at section 4 of the previous office action, The rejection under 35 USC 112/second paragraph made at section 8 of the previous office action.

Continuation of 13. Other: It is noted that the status identifiers for claims 4 and 5 are improper as neither claim was amended. The propoer status identifier should be "previously presented".

Attachment

1. Claims 1, 4 and 5 remain rejected under 35 USC 112/first paragraph as failing to comply with the enablement requirement, as set forth in section 6 of the previous office action. The response asserts that the method recited in claim 1 is not directed to diagnosing a particular variety of glaucoma in a certain ethnic/racial population, but is directed to providing information of the risk factor to individuals who have one of the claimed mutations. The response further asserts that the claimed method predicts whether open angle glaucoma may be one of the diseases that the individual may be afflicted with in the future and that it is not necessary to determine the relation between the claimed mutations with the particular type of glaucoma and the ethnic/racial status of the individual or to show a statistically significant number of individuals who presently shows sign of open angle glaucoma. These arguments have been thoroughly reviewed but were not found persuasive. As noted in the declaration by Yasuhiro Kouchi, the presence of each of the claimed mutations was found only once. However, the single occurrence of an alternate allele does not provide a predictable correlation that such polymorphism is associated with any single disease let alone the scope of diseases claimed. From a single occurrence, it cannot be determined whether the mutation is disease associated or is due to chance. Given the art accepted unpredictability of associating mutations in OPTN in broadly any population as well as any type of open angle glaucoma, the disclosure of a single occurrence in an unspecified patient population does not provide one of skill in the art that the mutation is a predictable risk factor for the scope of diseases claimed, let alone in any population. In the instant situation, not only does the specification not teach whether the frequency of the disclosed polymorphisms was statistically significant for one of skill in the art

to determine whether the occurrence is likely disease associated or due to chance, but the specification is also silent as to how many patients and controls were tested, what the ethnic/racial status of the patients and controls were and what type of open angle glaucoma (eg: POAG, JOAG) the patients suffered from. Given the evidence of unpredictability in the art regarding associating mutations in the same gene (OPTN) with POAG vs JOAG as well as in different racial populations, the specification does not enable one of skill in the art to practice the invention commensurate in scope with the claims without a large amount of unpredictable trial and error analysis. This experimentation is considered undue as it is unpredictable as to whether the mutations are a risk factor for disease, whether they are a risk factor in any patient population, and whether they are a risk factor for any type of open angle glaucoma.

The assertion that "Individuals who have one of the claimed mutations have a higher probability to be afflicted with open angle glaucoma, as compared to the general population" is not found persuasive as the specification has not provided a predictable association between the mutations claimed and risk for any specific type of open angle glaucoma. However, even if it had, the conflicting teachings of the art cited in the previous office action specifically exemplifies that even particular mutations which altered the amino acid sequence of optineurin and were found in multiple patients are unpredictably disease associated in different populations and different type of open angle glaucoma, as is broadly claimed. Here, the case is that a single alternative allele has been found. However, the study has not been independently replicated in different populations, with different types of open angle glaucoma, nor has any assessment been made as to whether the presence of the alternative allele is due to chance, or is actually disease

associated. For these reasons and the reasons made of record in previous office actions, the rejection is maintained.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jehanne Sitton
Primary Examiner
Art Unit 1634
11/28/06